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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0924]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 or send comments to Ron Otten, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Survey of Rapid Influenza Diagnostic Test (RIDT) Practices in Clinical Laboratories and Evaluation of Laboratory Course – Reinstatement (OMB Control No. 0920-0924) with change - the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain Office of Budget and Management (OMB) approval to reinstate with change, the data collection for the Survey of Rapid Influenza Diagnostic Test (RIDT) Practices in Clinical Laboratories (OMB Control No. 0920-0924). OMB approval for the 2012 RIDT project expired February 28, 2012. CDC seeks a three-year approval to conduct the RIDT project. Changes incorporated into this reinstatement request include changing the name of the collection to "Survey of Rapid Influenza Diagnostic Test (RIDT) Practices in Clinical Laboratories and Evaluation of Laboratory Course" and adding a question about whether or not the participants have taken the

free CDC rapid influenza testing course, Strategies for Improving Rapid Influenza Testing in Ambulatory Settings, and to rate the usefulness of the course in their clinical setting.

The Survey of Rapid Influenza Diagnostic Testing Practices in Clinical Laboratories and Evaluation of Laboratory Course is a national systematic study investigating rapid influenza diagnostic testing practices in clinical laboratories. The survey will be funded in full by the Office of Surveillance, Epidemiology, and Laboratory Services of the Centers for Disease Control and Prevention.

Influenza epidemics usually cause an average more than 200,000 hospitalizations and 36,000 deaths per year in the U.S. Respiratory illnesses caused by influenza viruses are not easily differentiated from other respiratory infections based solely on symptoms. Also influenza viruses may adversely affect different subpopulations.

The effective use of rapid influenza diagnostic testing practices is an important component of the differential diagnosis of influenza-like-illness in both inpatient and outpatient treatment facilities. Test results are used for making decisions about antiviral versus antibiotic use, and in making admission or discharge decisions. In many cases, rapid influenza tests are the only tests that can provide results while the patient is still present in the facility. Thus, the

appropriate use of the tests, and interpretation of test results is critical to the treatment and control of influenza. More than a dozen rapid tests have been approved by the U.S. Food and Drug Administration and are in widespread use. The reliability of rapid influenza tests is influenced by the individual test product used and the setting. Reported sensitivities range from 10-75%; while the median specificities reported are 90-95%. Other factors influencing accuracy are the stage (or duration) of illness when the diagnostic specimen is collected, type and adequacy of the specimen collected, variability in user technique for specimen collection or assay performance, and disease activity in the community. Given these and other collective findings, it is imperative for public health and for response planning that CDC develops sector-specific guidance and effective outreach to the clinicians on appropriate use of RIDT in their practices.

Previous studies by CDC of outpatient facilities showed that clinical laboratories usually perform the rapid tests for emergency departments, and provide results for both inpatient and outpatient treatment. Thus, understanding the use of rapid influenza testing in clinical laboratories in both hospitals and outpatient settings, how the results are reported to emergency departments, treatment facilities and health departments, and what quality assurance practices are used will guide future

efforts of the CDC to continue to develop and update appropriate influenza testing guidelines and sector-specific training materials for clinicians and improve health outcomes of the American public. In fact, CDC has developed a rapid testing course, "Strategies for Improving Rapid Influenza Diagnostic Testing", with continuing education credits that is available to clinicians and laboratorians free of charge. We would like to ask respondents to the survey if they have taken the course, and ask them to rate its usefulness.

The survey covers basic laboratory demographic characteristics, specimen collection and processing, testing practices, reporting of results to emergency departments and other treatment facilities, reporting results to health departments, quality assurance practices, and methods of receiving updated influenza-related information. The respondents would be clinical laboratory supervisors, nurses, and other clinicians. The majority of the questions request information about laboratory influenza testing practices. For this request, we have also added a question about whether or not the participants have taken the free CDC rapid influenza testing course and to rate its usefulness in their clinical setting.

No updated systematic study has been conducted to investigate how laboratories now use these tests, how they report results, or how they interact with outpatient treatment facilities,

whether they have taken the free rapid influenza testing course, or how they rate the course. The survey will be conducted on a national sample of laboratories and clinical facilities, including those in outpatient facilities that perform rapid influenza diagnostic tests. There are no costs to respondents except their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs)	Total Burden (in hrs)
Clinical Laboratory Supervisors	Survey of Rapid Influenza Diagnostic Test Practices in Clinical Laboratories	600	1	30/60	300
Nurses	Survey of Rapid Influenza Diagnostic Test Practices in Clinical Laboratories	600	1	30/60	300
Other Clinicians	Survey of Rapid Influenza Diagnostic Test Practices in Clinical Laboratories	600	1	30/60	300
				Total	900

DATE: March 28, 2013.

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Ron A. Otten,
Director, Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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